No. 14-1416

IN THE
UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

FERRING B.V.,

Plaintiff-Appellee,

v.

WATSON LABORATORIES, INC. – FLORIDA,

Defendant-Appellant,

APOTEX, INC. AND APOTEX CORP.,

Defendants.

Appeal from the United States District Court for the District of Nevada in case nos. 3:11-cv-00481-RCJ-VPC, 3:11-cv-00485-RCJ-VPC, 3:11-cv-00853-RCJ-VPC, 3:11-cv-00854-RCJ-VPC, 3:12-cv-01953-RCJ-VPC and 2:12-cv-01941-RCJ-VPC
Judge Robert C. Jones

CORRECTED NON-CONFIDENTIAL BRIEF FOR PLAINTIFF-APPELLEE FERRING B.V.

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2. The name of the real party in interest represented by me is:

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CONFIDENTIAL MATERIAL OMITTED

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STATEMENT OF RELATED CASES

This case is related to *Ferring B.V. v. Apotex, Inc. and Apotex Corp.*, Appeal No. 14-1377, which is currently pending before this Court. The present appeal results from a district court litigation that was consolidated with a suit against Apotex, Inc. and Apotex Corp. for pretrial proceedings and trial. These related cases involve the same patents-in-suit, but different defendants and different infringing Abbreviated New Drug Applications ("ANDAs"). Appeal No. 14-1377 is currently scheduled to be heard on June 10, 2014, along with the present appeal.

This appeal is also related to *Ferring B.V. v. Actavis, Inc., Watson Laboratories, Inc., Andrx Corp., Watson Laboratories, Inc. – Florida and Watson Pharma, Inc.*, Case No. 3:13-cv-00477 (D. Nev.), which involves the same ANDA, a damages claim regarding the patents at issue in this appeal, and an infringement claim regarding a different patent.

STATEMENT OF JURISDICTION

This Court has jurisdiction over *final* decisions in actions arising under any Act of Congress relating to patents. *See* 28 U.S.C. § 1295. While the district court's April 14, 2014 Order and Judgment states that it constitutes a "Final Judgment," that Judgment further references Findings of Fact and Conclusions of law that are "to be separately issued by the Court." *See* A325. Because such Findings have not yet issued and given the district court's recent scheduling of a status conference in the underlying litigation to take place May 28, 2014, it is not clear that the district court's Judgment is in fact final at this time as required by 28 U.S.C. § 1295.

STATEMENT OF THE ISSUES

1. Whether the district court correctly found that Watson's uncoated and coated tablet formulations infringe the asserted claims of the patents-in-suit and further correctly found that Watson failed to establish by clear and convincing evidence that the asserted claims of the patents-in-suit are obvious.

I. PRELIMINARY STATEMENT

This patent infringement case under the Hatch-Waxman Act concerns Ferring's Lysteda® product, the new modified release formulation of tranexamic acid that Ferring launched in 2010 as a treatment for heavy menstrual bleeding, or menorrhagia. Ferring's Lysteda® product lacks the limitations associated with prior therapies, including prior immediate release tranexamic acid formulations, which caused nausea, vomiting and diarrhea. The Lysteda® formulation delays the release of the active ingredient in the stomach in a manner that alleviates gastrointestinal side effects. Yet, at the same time, the Lysteda® formulation surprisingly delivers the active ingredient to the patient's bloodstream in a manner comparable to an immediate release formulation, making it bioequivalent to an immediate release formulation of the same dose. Thus, Lysteda® provides the benefits of an immediate release formulation while eliminating the gastrointestinal side effects associated with such formulations. Ferring's expert witnesses presented unrebutted testimony at trial that this surprising formulation design is unprecedented.

Ferring's Lysteda® product is therefore a unique and important discovery. The U.S. Food and Drug Administration ("FDA") recognized Lysteda® as a drug "intended . . . for the treatment of a serious or life-threatening disease or condition" that "demonstrates the potential to address unmet medical needs for such a disease

or condition." On that basis, the FDA granted the Lysteda® New Drug Application ("NDA") "fast track" status, thus providing expedited review of that application. Lysteda® is also disclosed and claimed in Ferring's U.S. Patent Nos. 7,947,739 ("the '739 patent"), 8,022,106 ("the '106 patent") and 8,273,795 ("the '795 patent"). (*See, e.g.*, A938.)

Watson argued at trial that its generic products are entirely different from Lysteda®. Watson in fact raised multiple implausible and contradictory arguments

in support of its theories of non-infringement and invalidity. For example, Watson argued at trial that the inactive ingredients in its uncoated tablets do not modify the release of the tranexamic acid notwithstanding repeated contrary statements in its ANDA and in its patent application disclosing its generic product. Watson further attempted to obfuscate its own expert's admissions that Watson's test results showed that its coated tablets meet the dissolution limitations of the patent claims, by attempting to raise new non-infringement theories at trial. Watson likewise attempted to introduce new alleged "prior art" references at trial in a futile effort to plug the multiple gaps in its invalidity theories.

In the end, following an 8-day bench trial, the district court properly rejected all of these arguments for the reasons set forth in the trial record. And, while the district court has not yet issued its Findings of Fact and Conclusions of Law supporting its Judgment, Watson's scattershot arguments on appeal do not demonstrate any error in these determinations. In fact, Watson either ignores or distorts the findings below and fails to even acknowledge the court's exclusion of alleged evidence Watson attempts to reassert on appeal. For these reasons and as further discussed below, this Court should affirm the district court's judgment.

II. STATEMENT OF THE CASE SETTING OUT THE FACTS RELEVANT TO THE ISSUES

Lysteda® is a novel and effective treatment for heavy menstrual bleeding, also known as menorrhagia. Prior to Lysteda®, available therapies for menorrhagia

offered limited efficacy and were associated with a range of side effects and other disadvantages. (*See, e.g.*, A797-A803; A018468-A018496; A018451-A018463.) For example, immediate release tranexamic acid formulations were associated with onerous gastrointestinal side effects, including nausea, vomiting and diarrhea. (*See, e.g.*, A018489-A018490; A018666-A018669; A778-A783, A801-A802, A930; A014893 at col. 1 lines 40-42; A014946 at col. 1 lines 38-40; A014998 at col. 1 lines 36-38.) These side effects are widely reported in package inserts relating to immediate release tranexamic acid formulations sold abroad. (*See, e.g.*, A765-A766, A930; A011496-A011498, A011501-A011503, A011506-A011507.) They are also reported in the literature. (*See, e.g.*, A016831-A016840; A012859-A012866; A018489-A018490.) For example, one study showed a statistically significant incidence of nausea in subjects who were administered an immediate release tranexamic acid formulation. (A018489.)

No immediate release formulation of tranexamic acid was ever approved by the FDA for treating menorrhagia in the United States. (*See., e.g.*, A018473.) Pharmacia obtained FDA approval in 1999 to market a 500 mg immediate release tranexamic acid formulation for the treatment of hemophilia and bleeding following tooth extraction. (*Id.*) The approved package insert for this formulation lists the same nausea, vomiting and diarrhea side effects associated with other immediate release formulations. (*See., e.g.*, A018498-A018503.) Pharmacia never

launched this formulation and ultimately withdrew its NDA. (A018473.)

A. The Formulations of the Patents-In-Suit Satisfy a Long-Felt Need for an Improved Treatment for Menorrhagia

In the early 2000s, Dr. Ralph Heasley and the other inventors on the patents-in-suit sought to develop an improved tranexamic acid formulation that would overcome the problems associated with immediate release tranexamic acid formulations. (*See, e.g.*, A759-A788, A797-A803; A018477-A018496.) Dr. Heasley and his colleagues sought to alleviate the gastrointestinal side effects associated with these formulations while also increasing the dosage strength to allow for efficacious three times daily dosing. (*See, e.g.*, A789-A791, A802-A804; A018477-A018496.) They further sought to achieve a formulation that could mimic the pharmacokinetic profile of an immediate release formulation and thereby provide the benefits associated with an immediate release formulation. (*See, e.g.*, A792-A793; A018477-A018496.) This involved a careful balancing of various formulation details and relied on the inventors' insight, explained in the patents-in-suit, that they could modify the release of the tranexamic acid from the formulation "to prevent a bolus of tranexamic acid being introduced into the stomach and available for dissolution in the gastric contents" while still delivering the active ingredient to the patient's bloodstream in a manner equivalent to an immediate release formulation. (*See, e.g.*, A783-A788; A014895 at col. 6 lines 3-24; A014948 at col. 5 line 66 - col. 6 line 20; A014998 at col. 1 line 51 - col. 2 line

5.) Dr. Heasley and his colleagues determined they could achieve their objective if they could devise a formulation that would modify the release of tranexamic acid in a manner that matched the rate of absorption in the gastrointestinal tract. (*See, e.g.*, A785-A787.)

Dr. Heasley and his colleagues ultimately succeeded in these efforts, developing a new modified release formulation of tranexamic acid that provides a higher per-tablet dose, is efficacious in treating menorrhagia while minimizing gastrointestinal adverse events, and is surprisingly bioequivalent to an immediate release formulation of the same dosage strength. (*See, e.g.*, A792-A795; A016832 ("A unique oral formulation of tranexamic acid (LYSTEDA) that provides a higher per-tablet dose and increases drug absorption time has been designed to maintain efficacy while minimizing gastrointestinal adverse effects and was recently approved by the U.S. Food and Drug Administration for the treatment of cyclic heavy menstrual bleeding.") These unexpected findings are disclosed in the patents-in-suit, which claim, *inter alia*, novel formulations of tranexamic acid and methods of using these formulations, and which cover Lysteda®. (*See, e.g.*, A807-A810, A966-A971; A014909-A014910 at col. 34 line 65 - col. 35 line 10; A014962-A014963 at col. 34 line 61 - col. 35 line 6; A015009 at col. 24 lines 18-30.)

B. The Asserted Patent Claims

Claim 1 of the ’739 patent is illustrative of the patent claims at issue in this appeal and states:

> 1. A tranexamic acid tablet formulation, comprising:
> tranexamic acid or a pharmaceutically acceptable salt thereof; and
> a modified release material, wherein the modified release material comprises a polymer selected from the group consisting of hydroxyalkylcelluloses, alkylcelluloses, cellulose ethers, partial esters thereof, and mixtures thereof;
> wherein the modified release material is present in the formulation in an amount from about 10% to about 35% by weight of the formulation;
> wherein the formulation provides an in-vitro dissolution release rate of the tranexamic acid or pharmaceutically acceptable salt thereof, when measured by the USP 27 Apparatus Type II Paddle Method @ 50 RPM in 900 ml water at 37±0.5°C., of less than about 70% by weight tranexamic acid or pharmaceutically acceptable salt thereof released at about 45 minutes, and about 100% by weight tranexamic acid or pharmaceutically acceptable salt thereof released by about 120 minutes; and
> wherein each tablet of the formulation provides a dose of about 650 mg of tranexamic acid.

(A014927.)

As discussed below, Watson’s non-infringement arguments are limited to only two limitations of claim 1 and the other asserted patent claims. The first of these limitations is the “modified release material.” For example, claim 1 of the ’739 patent requires the presence of a modified release material, and further

specifies that this modified release material is present in "an amount from about 10% to about 35% by weight of the formulation" and that it "comprises a polymer selected from the group consisting of hydroxyalkylcelluloses, alkylcelluloses, cellulose ethers, partial esters thereof, and mixtures thereof." (A014927 at col. 69 lines 49-53.) Other claims of the patents-in-suit vary the specified amount of modified release material (*e.g.*, from about 5% to about 50%) or require a specific polymer (*e.g.*, hydroxypropylmethylcellulose). (*See, e.g.*, A015015 at col. 35 lines 21-49; A014928 at col. 71 line 16 – col. 72 line 4.)

Thus, these limitations relating to the modified release material define, in part, the composition of the claimed tranexamic acid tablet formulation, requiring the presence of at least one polymer from the recited group and further requiring that the modified release material constitutes a specific percentage by weight of the formulation. Aside from these limitations, however, the specification teaches that the modified release material may broadly comprise a wide range of other ingredients, including "diluents," "coloring agents, flavoring agents, lubricants," and "other tableting aids" that may be included along with the recited polymers. (*See, e.g.*, A014903 at col. 21, lines 47-62.) The specification further teaches that the modified release material and tranexamic acid active ingredient may "provide[] a compressed tablet that may or may not be film coated." (*Id*. at col. 21, lines 1-2.)

The second limitation Watson has challenged is the dissolution limitation of the asserted patent claims, which specifies the rate of release of the tranexamic acid active ingredient from the claimed formulation. For example, claim 1 of the '739 patent requires a particular "in-vitro dissolution release rate" when measured using a specific testing apparatus and method set forth in the United States Pharmacopeia ("USP"), namely the USP 27 Apparatus Type II Paddle Method at 50 RPM in 900 ml water at 37±0.5° C. (A014927 at col. 69 lines 57-65.) Employing these test conditions, claim 1 requires that the formulation release less than about 70% by weight tranexamic acid or pharmaceutically acceptable salt thereof at about 45 minutes, and about 100% by weight tranexamic acid or pharmaceutically acceptable salt thereof by about 120 minutes. (*Id*.) Other patent claims recite different dissolution limitations requiring less than about 40% by weight tranexamic acid or pharmaceutically acceptable salt released at about 15 minutes, less than about 70% by weight tranexamic acid or pharmaceutically acceptable salt released at about 45 minutes, and not less than about 50% by weight tranexamic acid or pharmaceutically acceptable salt released by about 90 minutes. (*See, e.g.*, A014979-A014980 at col. 68 line 60 – col. 69 line 21; A015015 at col. 35 lines 21-49; A018674.)

C. The FDA Grants Lysteda® Fast Track Designation

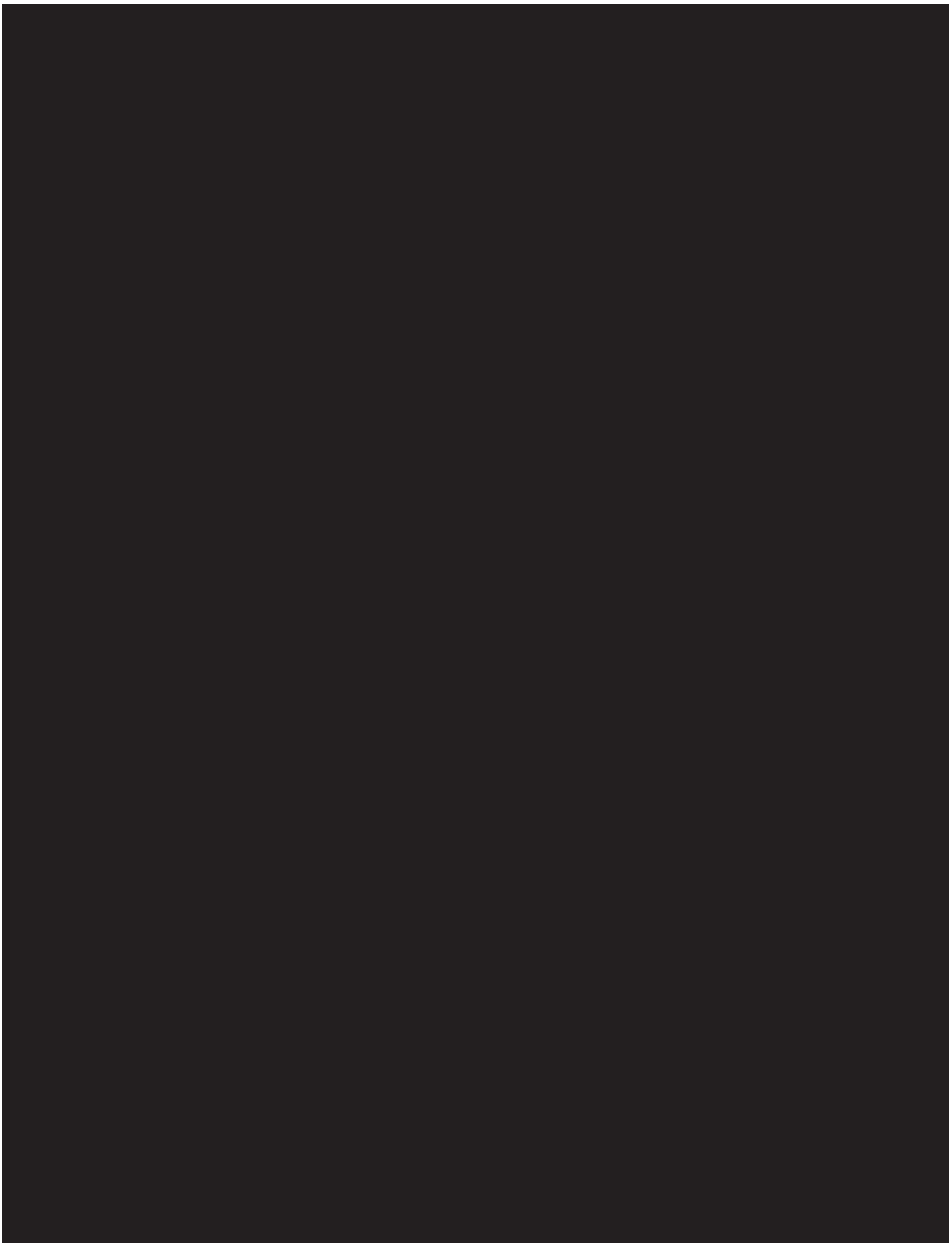
Having devised the formulations of the patents-in-suit, Dr. Heasley and his colleagues at Xanodyne Pharmaceuticals, Inc. ("Xanodyne") proceeded with seeking FDA approval of what would later become Lysteda®. Given the significant unmet need for the treatment of menorrhagia and the superior properties of the Lysteda® formulation as compared to existing treatments for this disorder, Xanodyne applied for and received "fast track designation" for its NDA under 21 U.S.C. § 356. (*See, e.g.*, A018451-A018463; A018449; A804-A807.) The Lysteda® NDA thus enjoyed expedited review by the FDA based on the FDA's determination that Lysteda® was "intended . . . for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition." *See* 21 U.S.C. § 356(b)(1).

The FDA approved Lysteda® in 2009, and at the time of approval, Lysteda® was the only non-hormonal drug approved for the treatment of menorrhagia in the United States. (*See, e.g.*, A103; A018030, A018033.) The approved labeling for Lysteda® provides summary results of the clinical studies conducted in support of the Lysteda® NDA. (*See, e.g.*, A012954-A012965.) These results show that, unlike immediate release tranexamic acid formulations, Lysteda® is not associated with the gastrointestinal side effects nausea, vomiting and diarrhea. (A012955 (Table 2 reporting adverse events, which does not include nausea, vomiting and

diarrhea); *see also, e.g.*, A941; A016840.) Recognizing the value of Lysteda® and the associated intellectual property, Ferring purchased these assets from Xanodyne in 2010 and began marketing Lysteda® in the United States for treatment of menorrhagia. (*See, e.g.*, A012951-A012970.)

D. Watson's Generic Tranexamic Acid Tablets

[redacted]



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Confidential Material Redacted

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[1] Ferring presented unrebutted evidence that Watson's uncoated tranexamic acid tablets at 17 kp hardness meet the dissolution limitations of the patent claims. Notably, for Watson's *coated* tranexamic acid tablets, the tablet dissolution is further modified by the coating and thus the hardness of the tablet core is not determinative of which coated tablets infringe. Ferring's evidence of infringing coated tablets is therefore not limited to any specific hardness level.

E. Patent Litigation Proceedings

In 2011, Watson notified Ferring that it was challenging Ferring's patents that cover Lysteda®. (*See, e.g.*, A018218-A018233; A018234-A018248; A018249-A018259.) Ferring filed suit against Watson within the 45-day period provided under the Hatch-Waxman Act. (A100-A106; A130-A137; A179-A185.) The actions against Watson were eventually consolidated with separate actions against Apotex Inc. and Apotex Corp. (collectively, "Apotex"). (*See, e.g.*, A205-

A206.)

1. Claim Construction

During *Markman* proceedings, Watson sought multiple claim constructions differing from the plain and ordinary meanings of the terms at issue. For example, Watson proposed the following narrow construction of "modified release material":

> A polymer selected from the group of hydroxyalkylcelluloses, alkylcelluloses, cellulose ethers, or partial esters thereof that acts to slow the release of tranexamic acid in the water medium used in the 27 USP Apparatus Type II test.

(*See, e.g.*, A195-A196.) This proposal thus reads into "modified release material" the specific polymers listed later in the claims and reads out the open-ended construction afforded by the word "comprises"—"wherein the modified release material ***comprises*** a polymer selected from the group consisting of . . ." (*See* A014927 at col. 69 lines 49-53; *see also* A016475-A016479.) This proposal further incorporates into "modified release material" elements of the dissolution testing conditions specified in the separate dissolution limitations.

Ferring, by contrast, argued that "modified release material" should be construed according to its plain and ordinary meaning—*i.e.*, material that modifies the release of the active pharmaceutical ingredient. (*See, e.g.*, A015501-A015504; A016475-A016479.) As Ferring explained, the claims elsewhere specify the

polymers that may "comprise" the modified release material and also the dissolution limitations and associated test conditions for assessing the tablet formulation. (*See, e.g.*, A016475-A016476.) Ferring argued that these separate limitations should not be read into and conflated with the phrase "modified release material." (*See, e.g., id.*) Ferring further argued that the term "comprises" should not be read out of the claims as Watson had proposed. (*See, e.g., id.*)

As for the dissolution limitations, Watson largely agreed with Ferring and relied on the position of Watson's expert, Dr. Palmieri, [redacted]

[redacted]

(A018541-A018542 at ¶¶ 1, 2, A018545 at ¶¶ 15, 17 (emphasis added).)

Thus, while Watson later attempted to argue that the USP test method in the patent claims requires the testing of 6 test samples, it took a different position during claim construction proceedings, that the testing is properly performed on individual

samples.

The district court agreed with Ferring, rejecting each and every construction Watson proposed, including its construction of "modified release material." (*See, e.g.*, A015478-A015479; A194-A204.) Indeed, the district court explicitly noted, and rejected, Watson's improper attempt to conflate modified release material and the dissolution limitations of the claims. (*See, e.g.*, A015449:8-12; A195-A196.)

2. Watson's At-Risk Launch

Before the district court's claim construction order issued, Watson launched its generic tranexamic acid products at risk. (*See, e.g.*, A14848-A14851.) Watson also did so even though the parties had not initiated expert discovery and Watson had not yet produced any commercial samples of its generic tablets for testing by Ferring.

Watson subsequently produced some samples post-launch, in late February, 2013, and also in March and June, 2013. These samples included Watson's final coated tablets as well as its uncoated tablets. Watson refused to provide information about the hardness levels at which these uncoated tablets were compressed, despite that batch records for these tablets show that Watson continually monitors hardness levels throughout the manufacturing process. (*See, e.g.*, A2014-A2015.)

Watson and Ferring each conducted dissolution testing of these samples

during expert discovery, with Watson and Ferring each employing two separate laboratories to test the samples. The results from each of these four laboratories showed that Watson's coated generic tranexamic acid tablets meet the dissolution limitations of the patent claims. (*See, e.g.*, A018424-A018425; A018426-A018437; A018438-A018445; A018285-A018291; A1000-A1007.) [redacted]

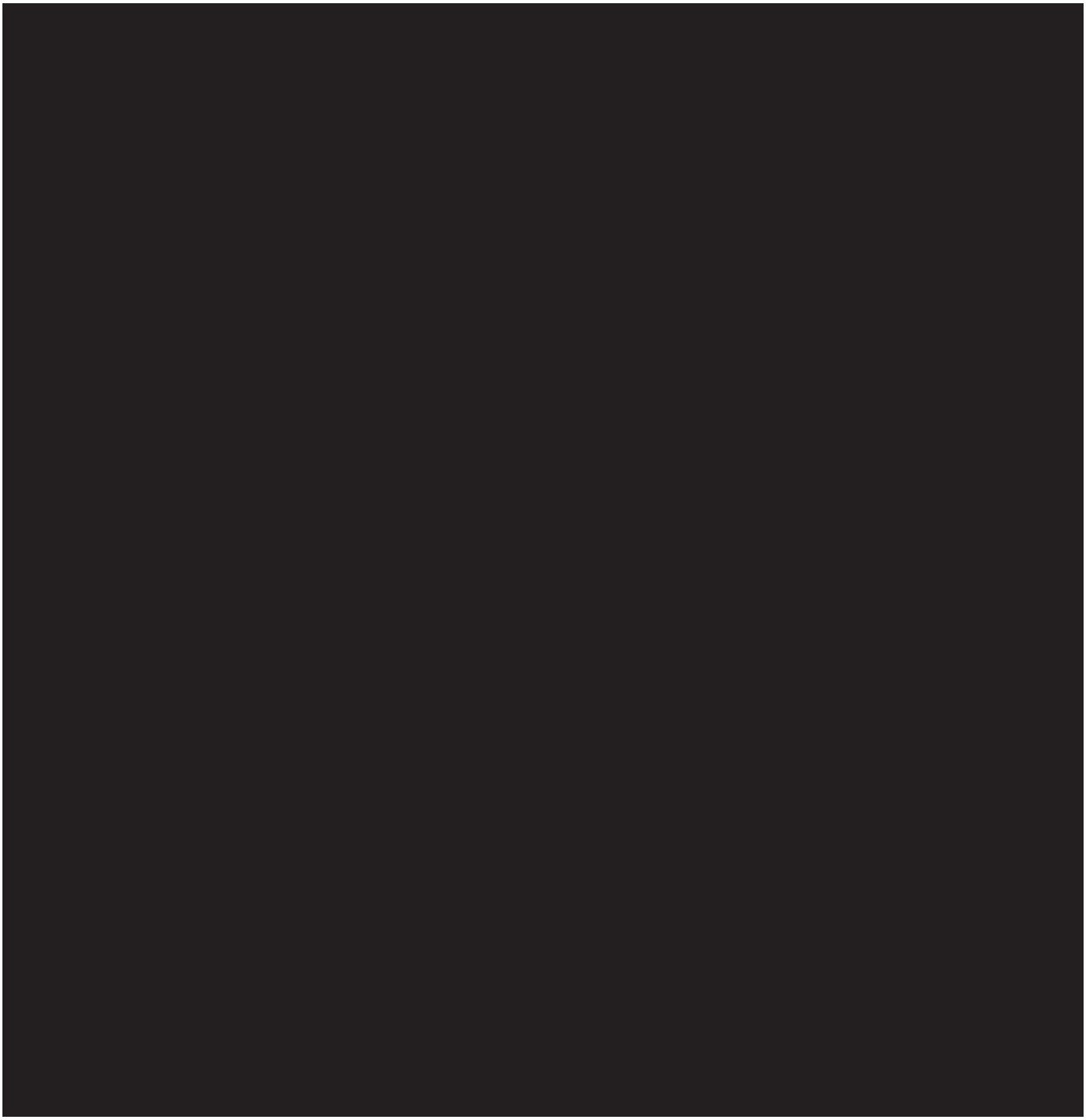
[redacted] Ferring thus relied at trial on Watson's testing of its ANDA bioequivalence batch, which specified the hardness of the tested tablets. (*See, e.g.*, A14840; A991-A993, A2003-A2011.)

F. The District Court Found Watson's ANDA Infringes Ferring's Patents

Watson raised only two non-infringement arguments at trial: (1) that Watson's generic tranexamic acid tablets allegedly do not contain a "modified

release material" in the amount required by the asserted claims; and (2) that Watson's generic tranexamic acid tablets allegedly do not meet the dissolution limitations of the asserted claims. (*See, e.g.*, A018037:2-8.) The district court rejected both of these arguments, finding that Watson's uncoated and coated tablets meet all of the limitations, and thus each infringe the asserted claims. (*See, e.g.*, A2307-A2311; A325-A327.)

Regarding the first issue, Ferring presented evidence at trial that both Watson's coated and uncoated tablets contain a modified release material as required by the asserted claims. (*See, e.g.*, A013877, A013880-A013882; A951-A954, A956-A958, A972-A983, A998-A999, A1990-A1993, A2012-A2014; A014050-A014051 at ¶¶ 8-10, 19-20; A2736-A2738 at 44, 49, 51-54; A2705-A2706 at 59-61, 64-65.) [redacted]



Watson failed to dispute any of these points. Instead, Watson pointed to dissolution test data from uncoated tablets of unspecified hardness and argued that

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[2] The '795 patent claims do not specify the inclusion of any specific polymer in the modified release material.

its uncoated tablets behave like immediate release products. (*See, e.g.*, A018041:3-5.) Watson therefore contended that they must not contain modified release material. (*See, e.g.*, *id*.) Watson never reconciled this argument, however, with the statements in its own ANDA, patent application and from its formulators that the various components in its tablets act to modify the release of tranexamic acid. Watson also failed to rebut Dr. Williams' testimony that the blend of hypromellose, glyceryl behenate, and other materials in Watson's uncoated and coated tablets in fact modifies the release of the tranexamic acid active ingredient. (*See, e.g.*, A951-A954, A1999.)

As for its coated tablets, Watson conceded that they contain modified release material as required by the patent claims. (*See, e.g.*, A018041:1-3.) Watson argued, however, that the modified release material is present in too small of an amount because the ingredients in its uncoated tablets (which Watson calls "cores") allegedly do not act as release modifiers. (*See, e.g.*, A018041:5-10.) As noted above, however, Watson's arguments that its uncoated tablets do not contain a modified release material is contradicted by its own ANDA, its own patent application, and statements by its own formulators.

The evidence introduced at trial also established that both Watson's coated and uncoated tablets meet the dissolution limitations of the asserted claims. For example, dissolution data Watson generated from the batch of tablets it used in its

ANDA bioequivalence study show that uncoated tablets compressed to a hardness of 17 kp meet the dissolution limitations of the asserted claims. (*See, e.g.*, A14840; A991-A993, A2003-A2011.) Watson did not dispute that these test results meet the dissolution limitations of the patent claims and instead offered speculative testimony that the data were based on an experimental batch. The district court did not accept this unsupported argument.

As for Watson's coated tablets, as noted above, data from *four* different laboratories, including Watson's own internal lab, show that these coated tablets meet the dissolution limitations of the patent claims. (*See, e.g.*, A018424-A018425; A018426-A018437; A018438-A018445; A018285-A018291; A1000-A1007.) [redacted] Watson nevertheless attempted to downplay these test results by arguing that not every one of the samples Watson produced for testing met the dissolution limitations. Watson offered this argument even though the undisputed test results show that a substantial percentage of the limited samples that Watson produced for testing in fact meet the limitations of the patent claims. (*See, e.g.*, A018424-A018425; A018426-A018437; A018438-A018445; A018285-A018291; A1000-A1007; A2212-A2215.) In particular, considering only data that Watson itself generated, two of the twelve tablets tested

from each of commercial lots 3 and 4 met the limitations of the asserted claims of the ’106 and ’795 patents. (*See* A018424-A018425; A1001-A1002; A018898; A018426-A018437; A1000-A1001; A018896; A2214:15-18.) Thus, by Watson’s own testing of the limited samples it selected in this action, 16% of the samples for each of these two commercial lots met the dissolution limitations of these patent claims.

Watson additionally attempted to refute this evidence of infringement by raising the new argument at trial that the USP test method recited in the patent claims required the testing of six samples and therefore Ferring could not rely on the test results from individual tablets to show infringement. Ferring noted in response that this argument conflicted with Watson’s position during claim construction proceedings that the USP dissolution test was properly performed on individual tablet samples. (*See, e.g.*, A924-A925; A018541-A018542 at ¶¶ 1, 2, A018545 at ¶¶ 15, 17.) Moreover, Watson’s arguments in this regard relied on the “Acceptance Table” in the USP, which relates to dissolution specifications in product monographs that specify a “Q” value. Watson had not presented this theory during expert discovery and, in any event, the patent claims do not reference any product monograph or recite any “Q” value. (*See, e.g.*, A921-A924; A1508-A1511.) The district court therefore excluded any expert testimony based on the “Acceptance Table.” (A1508-A1511.)

Based on the foregoing evidence, the district court concluded that Watson's ANDA allows for the production of uncoated and coated tranexamic acid tablets that infringe the asserted patent claims. (*See, e.g.*, A2307-A2311; A325-A327.)

G. Post-Trial Activities

The district court announced its findings of infringement from the bench at the close of trial and indicated that it would enter an injunction in connection with these findings. (*See, e.g.*, A2307-A2311.) Watson then submitted a flurry of post-trial motions, including a motion to reconsider entry of an injunction.

[redacted] And Watson entirely ignored that Ferring's proven claims of infringement as to its coated tablet formulations are not limited by tablet hardness. The district court declined to consider this alleged evidence introduced post-trial. (*See, e.g.*, A285-A288.)

Watson additionally argued in its reconsideration motion that injunctive relief allegedly was not appropriate without first considering the factors enumerated in the Supreme Court's decision in *eBay*, including irreparable harm. (*See* A018050-A018051.) Ferring disputed that any such showing was necessary

for relief under 35 U.S.C. § 271(e), which was not addressed in *eBay*. (*See, e.g.*, A018205-A018206.)

The district court fully considered Watson's arguments and submissions, including detailed information about Ferring's Lysteda® sales before and after Watson's generic launch. (*See, e.g.*, A285-A290; A018090.) Based on this evidence, the court specifically rejected Watson's argument that "Ferring will not be irreparably harmed by a stay" of the court's judgment and associated relief. (*See, e.g.,* A322-A323; A285-A290.) The court addressed and rejected each of Watson's arguments that an injunction was allegedly not appropriate in light of *eBay* because Ferring allegedly had not suffered and would not suffer irreparable harm. (*See, e.g., id*.) The court further detailed the harm Ferring stood to suffer going forward if Watson were to remain on the market. (*See, e.g., id*.) For example, the court noted that this harm is "not purely economic, but also in the loss of good faith with the consuming public that comes from being an innovator with an exclusive product." (A322.)

Finally, Watson raised multiple specific objections to the detailed proposed Findings Ferring had submitted summarizing the district court's determinations at trial. (*See* A018097-A018138, A018164-A018199; A294-A297.) The district court considered, and rejected, each of these objections and stated that its Judgment and Findings would issue. (*See, e.g.*, A294-A297.) On April 14, 2014,

the district court entered its Judgment, and in that Judgment indicated its supporting Findings of Fact and Conclusions of law would "be issued separately by the Court." (A325 at ¶ 1.) Without waiting for those Findings, Watson appealed from the district court's Judgment the same day it was entered, April 14, 2014. (A328-A330.) The district court has not yet issued its Findings but has set a Status Conference in this case for May 28, 2014, during which it may provide additional information about those Findings. (A018209.)

In light of the statement in its Judgment that its Findings would issue separately and also the district court's recent setting of a status conference, Ferring moved this Court to stay the present appeal pending the district court's issuance of its Findings. (D.I. 28.) The Court denied Ferring's motion on May 12, 2014. (D.I. 32.)

III. SUMMARY OF ARGUMENT

Watson's numerous arguments on appeal do not establish any errors in the district court's judgment that the asserted patent claims are valid and infringed. In the proceedings below, Watson raised only two non-infringement arguments in response to Ferring's arguments that its uncoated and coated tablets infringe the asserted claims of the patents-in-suit: (1) that its uncoated and coated tablets do not contain a modified release material as required by the patent claims; and (2) that its

uncoated and coated tablets do not meet the dissolution limitations of the patent claims. Watson repeats these same flawed arguments on appeal.

Watson's uncoated tablets contain the same hypromellose polymer as Example 1 of the patents-in-suit, and its own ANDA documents and patent application detail how this and other ingredients in Watson's uncoated tablets modify the release of the tranexamic acid active ingredient. Watson's arguments that its uncoated tablets are actually immediate release products cannot refute this evidence and, in any event, improperly conflate the modified release material limitation with the separate dissolution limitations. Watson likewise cannot refute the evidence of record showing that its uncoated tablets of 17 kp hardness meet the dissolution limitations of the patent claims.

Watson's arguments directed to its coated tablets fail for similar reasons. Watson concedes that its coated tablets contain a modified release material but contends that this modified release material is not present in the amount required by the patent claims because only the polymers in Watson's tablet coating may be considered part of the modified release material. Watson's ANDA and patent application, however, as well as admissions by its scientists, establish that the components in Watson's uncoated tablet cores also act to modify the release of the active ingredient and thus are part of the modified release material in Watson's coated tablets. And, again, Watson cannot refute the test data showing that its

coated tablets meet the dissolution limitations of the asserted patent claims.

[redacted]

Watson also failed to show, by clear and convincing evidence, that the asserted claims are invalid as obvious. Watson offers a series of conclusory and unsupported arguments that the multiple limitations of the patent claims were disclosed in or suggested by the prior art. The evidence does not support any such assertion. No prior art reference discloses or suggests tranexamic acid formulations of the dosage strength or composition, or having the dissolution profile as described in the asserted patent claims. Moreover, Ferring presented undisputed evidence at trial that the unique formulation design of the patents-in-suit is unprecedented.

IV. ARGUMENT

A. The District Court Correctly Found that Watson's Generic Tranexamic Acid Products Infringe Ferring's Patent Claims

This Court reviews a district court's findings of infringement for clear error and thus will not disturb such findings absent a definite and firm conviction that a mistake has been committed. *See, e.g., Otsuka Pharm. Co., Ltd. v. Sandoz, Inc.*, 678 F.3d 1280, 1290 (Fed. Cir. 2012). As discussed in more detail below, the trial

record more than adequately supports the district court's findings of infringement, and Watson has raised no reasonable argument to the contrary. (*See, e.g.*, A915-A1039, A1264-A1268, A1286-A1308, A1324, A2159-A2161, A1990-A2024; A018670, A018672-A018736; A018918-A018941.)

1. Watson's Uncoated Tablets Infringe the Asserted Claims of the Patents-in-Suit

a. Watson's Uncoated Tablets Contain a Modified Release Material

Watson's ANDA describes how it chose the type and amount of inactive ingredients in its uncoated tablets such that they would release the tranexamic acid active ingredient "[n]either too fast [n]or too slow." (A013880-A013882; A972-A983.) And this blend of ingredients is present in the amount required by the patent claims and includes hypromellose, one of the specific types of polymers specified by the '739 and '106 patent claims. (*See, e.g.*, A951-A953; A981-A983; A1999.)

Watson nevertheless contends that its uncoated tablets cannot contain a modified release material as required by the asserted patent claims because they allegedly exhibit immediate release dissolution profiles. While this argument is factually incorrect, it also improperly and confusingly conflates the modified release material and dissolution limitations of the patent claims. (*See, e.g.*, Watson's Br. at 33-36.) The district court rejected this flawed construction of

modified release material, and Watson has failed to show any error in that determination. (*See, e.g.*, A195-A196; A015478-A015479; A015449:8-12.)

Disregarding the district court's rejection of its claim construction position, Watson points to portions of the patent specifications discussing the dissolution profiles associated with "immediate release oral dosage form[s]" and "modified release oral dosage form[s]" to argue that its uncoated tablets do not contain a modified release material. (Watson's Br. at 34.) This argument again improperly conflates the distinct dissolution and modified release material limitations, by attempting to attribute a dissolution profile to the modified release material. This argument is also misleading because this section of the specification does not concern the term "modified release material," which is discussed elsewhere. (*See, e.g.*, A014903 at col. 21 lines 47-62.) Rather, this discussion concerns certain exemplary "oral dosage forms" as a whole, and their dissolution profiles, and not the properties of the modified release material or any other portions of those dosage forms. (*See* A014899 at col. 14 lines 26-27 ("A 'modified release dosage form' for purposes of the present invention is an *oral dosage form* . . ." (emphasis added).) These exemplary dosage forms are also not referenced in any of the patent claims, which do not use these terms.

Watson's citation to Dr. Williams' trial testimony likewise reflects its repeated efforts to confuse this issue by conflating the modified release and

dissolution limitations. The testimony Watson cites concerns whether specific test results depict immediate release dosage forms. When Dr. Williams was directly asked, however, whether Watson's uncoated tablets contain a modified release material as required by the patent claims, his testimony was unequivocal:

> Q **Let's now discuss Dr. Maurin's opinions on the amount of modified release material in Watson's generic tranexamic acid tablets. Did you hear Dr. Maurin testify that only the excipients in the color coating of Watson's generic tranexamic acid tablets constitute the modified release material in these products?**
>
> A **That's what I understood, yes. I heard him.**
>
> Q **Do you agree with Dr. Maurin?**
>
> A **I do not.**
>
> Q **Would you explain the basis for your disagreement with Dr. Maurin referencing PTX 381 about which you testified in Ferring's case in chief.**
>
> A **So, in my opinion, it's not just the color coating because Watson uses in their granules a hypromellose as well as another material called glyceryl behenate, and glyceryl behenate is hydrophobic, and both of those can, along with the other ingredients in there as I've testified to, modify the release of drug, and that is displayed here.**

(A1999.)

Dr. Williams' opinion that Watson's uncoated tablets contain a modified release material as required by the asserted patent claims is well supported by the

evidence of record including statements in Watson's ANDA, and Watson's patent application, as well as the admissions of its own formulators indicating that the combination of ingredients in Watson's uncoated tablets in fact modify the release of the tranexamic acid. (*See, e.g.*, *supra* at Section (II)(D)(1).) Indeed, Watson's own patent application states that its uncoated tablets comprise "tranexamic acid and a modified release material." (A014050 at ¶¶ 9-10; *see also, e.g.*, A977-A979, A1990-A1993, A2012-A2014; A2738 at 51-52; A2706 at 64-65.)

Finally, Watson wrongly contends that "it is not clear that the district court actually applied its stated claim construction of 'modified release material.'" (Watson's Br. at 38.) The only confusion, however, is that created by Watson's repeated conflation of the dissolution and modified release material limitations. The district court correctly assessed these limitations separately and found that Watson's uncoated tablets contain modified release materials, as required by the asserted patent claims, and also meet the dissolution limitations of the patent claims.[3]

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[3] Watson also contends that Ferring argued for a new definition of "modified release material" in its opposition to Watson's motion for stay, in allegedly arguing that only the hypromellose polymer constitutes the modified release material in Watson's infringing tablets. (Watson's Br. at 39.) Watson is incorrect. Indeed, Ferring discussed that Watson's uncoated tablets contain tranexamic acid "and inactive ingredients *including* hypromellose" and thus has always asserted that the

(continued…)

b. Watson's Uncoated Tablets Meet the Dissolution Limitations of The Asserted Claims

The district court properly found infringement based on the dissolution tests conducted by Watson on the uncoated tablets used in connection with its ANDA bioequivalence study. (*See, e.g.*, A14840; A991-A993, A2003-A2011.) Specifically, Watson's own internal testing shows that uncoated tablets 17 kp hardness meet the dissolution limitations of the asserted patent claims. (*See, e.g.*, *id.*) Watson does not dispute this. Instead, Watson attempts to distract from and downplay these results in a series of arguments, including that other tablets allegedly yield different dissolution results, that testing on the bioequivalence tablets allegedly is unreliable, and that the district court allegedly did not consider Watson's full ANDA. For at least the reasons discussed below, each of these arguments fails.

Watson's primary argument on appeal is the same misleading argument the district court rejected below. Watson contends that certain uncoated tablets that it selected for testing in this litigation do not meet the dissolution limitations of the patent claims and thus do not infringe. But Watson's test results cannot refute the test results on Watson's ANDA bioequivalence batch indicating that Watson's uncoated tablets of 17 kp hardness meet the dissolution limitations of the patent

(…continued)
blend of polymers and other ingredients constitutes the modified release material. (D.I. 13 at 4.)

claims. That is because Watson refused to identify the hardness of the uncoated tablets it produced for testing in this litigation even though it monitors hardness levels throughout the manufacturing process. (*See, e.g.*, A2014-A2015.) Watson thus never identified any other test data associated with an uncoated tablet of 17 kp hardness despite the fact that Watson's own documents showed that Watson did in fact manufacture and collect samples of commercial batches at 17 kp hardness in recent scale-up studies. (*See, e.g.*, A996-A997; A013528.) The district court thus properly disregarded Watson's arguments that test results relating to its uncoated tablets of unspecified hardness somehow refuted the results on Watson's bioequivalence tablets.

Second, while Watson does not dispute that the test data concerning its ANDA bioequivalence batch meet the dissolution limitations of the patent claims, Watson argues this data is suspect because it allegedly "is not part of the ANDA" and "was created before scale-up." (Watson's Br. at 45.) Watson ignores, however, that this data was conducted by Watson's own laboratories on the tablets generated for its bioequivalence study. (*See, e.g.*, A014840; A991:9-18, A2010-A2011.) In other words, this batch was used in studies conducted to establish Watson's generic product is bioequivalent to Lysteda® and thus is the very basis for the FDA's approval of Watson's ANDA.

The district court also did not accept Watson's related arguments that the properties of its generic tranexamic acid products changed during scale up, and Watson has not identified any error in that determination. As Dr. Williams explained, an important goal of scale-up activities is to maintain the same composition and attributes as the smaller scale batches, such as the ANDA batch. (*See, e.g.*, A986-A988; A1266-A1268; A1996-A1998.) Dr. Williams further observed that Watson's own FDA submissions indicated that Watson's products maintained these properties during scale-up. For example, Watson's Process Development Report states that "the addition of additional alcohol during wet granulation generated the most promising dissolution that most closely resemble[d] that of the ANDA batch." (A013504; A987-A988.)

Watson additionally alleges that the district court did not consider Watson's full ANDA in concluding that its uncoated tablets infringe the asserted patent claims. (*See, e.g.*, Watson's Br. at 42-44.) In advancing this argument, Watson misleadingly cites to a part of the trial transcript in which the district court was trying to understand what is included in the "application" part of an ANDA. The record, however, demonstrates that the district court considered Watson's full ANDA, including amendments to its specifications. For example, as discussed above, Watson's original ANDA contained a hardness specification of 13-20 kp for its uncoated tablets. (*See*, *e.g.*, A013885; A984, A989.) When requesting final

approval of its ANDA, Watson submitted a "minor amendment" that included a tightening of the specification from 13-20 kp to 13-17 kp. (*See, e.g.*, A013565; A013912-A013920; A013789; A995-A996.) The district court explicitly stated that "in this case is…the act of infringement has to be measured inclusive of your limitation of 13 to 17 kp." (A2256.) Watson's argument that the district court failed to consider such amendments is simply unfounded.

Watson also contends that the district court improperly refused to consider the note to its manufacturing personnel to adjust the compression to maintain the hardness below 16 kp. (Watson's Br. at 44; *see* A018512.) The district court correctly determined, however, that this note did not amend Watson's ANDA drug product specification and therefore properly excluded testimony concerning that issue and Watson has not shown any error in that determination. (*See, e.g.*, A1450:9-22.) This manufacturing note does not prohibit Watson from producing uncoated tablets within the full range of 13-17 kp. Indeed, Watson's own FDA expert conceded that Watson has obtained FDA approval to manufacture its generic tranexamic acid tablets at a hardness range that includes 17 kp. (*See, e.g.*, A996:10-18.) And Watson's argument that there is no evidence that Watson "ever made or sold" a 17 kp tablet is wrong. As noted above, Watson has manufactured tablets at 17 kp and its own batch records detail commercial batches manufactured

at hardness levels greater than 16 kp. (*See, e.g.*, A017539; A014840; A996-A997; A013528.)

Finally, Watson separately contends that its alleged post-trial ANDA amendment, which supposedly limits its hardness specification to 13-16.5 kp, establishes that its uncoated tablets do not infringe Ferring's patent claims. (Watson's Br. at 53-54.) The district court properly refused to accept this new alleged evidence offered post-trial and, again, Watson does not show any error in this determination. (*See, e.g.*, A285-A288.)

For at least the reasons above, Watson's uncoated tablets meet all the claim limitations and therefore infringe the assert claims.

2. The District Court Properly Found That Watson's Coated Tablets Infringe the Patents-in-Suit

a. Watson's Coated Tablets Contain a Modified Release Material

Watson concedes that its coated tablets contain modified release material. (*See, e.g.*, A018041:1-3.) Watson contends, however, that they do not contain the amount of modified release material required by the patent claims because only the coating should be considered in assessing the amount of modified release material. Watson does not identify any support for construing the claims such that it may assess whether individual components of its tablets act as a modified release material. And the patent claims and specification indicate exactly to the contrary.

They teach that the modified release material comprises one or more of the specified polymers and may be employed in combination with various other inactive ingredients including "diluents," "coloring agents, flavoring agents, lubricants," and "other tableting aids". (A014903 at col. 21 lines 47-62.) The claims and specification thus reflect the fact that the formulation of the tablet as a whole acts to modify the release of the active ingredient. (*See, e.g.*, A951-A954, A1999.) The specification further explicitly teaches that "the modified release material may be incorporated into a coating applied onto, e.g., a tablet . . . incorporated into a matrix. . . or a combination thereof." (A014899 at col. 13 line 65- col. 14 line 3.) Here, it is undisputed that Watson's coated formulation as a whole modifies the release of the active tranexamic acid ingredient and thus the formulation includes a modified release material as required by the patent claims.

Moreover, even if it were appropriate to separately consider the coating and Watson's uncoated tablet core, which it is not, this argument would fail for the same reasons that its arguments regarding its uncoated core tablets fail. For example, as discussed above, Watson's ANDA, patent application and the testimony of its formulators all indicate that the materials used in Watson's uncoated tablet cores modify the release of the active ingredient. (*See, e.g.*, A013877, A013880-A013882; A951-A954, A956-A958, A972-A983, A1990-A1993, A2012-A2014; A014050-A014051 at ¶¶ 8-10, 19-20; A2736-A2738 at 44,

49, 51-54; A2705-A2706 at 59-61, 64-65.) And this evidence was further corroborated by Dr. Williams.

b. Watson's Coated Tablets Meet the Dissolution Limitations of The Asserted Claims

Four different laboratories tested Watson's commercial tablets and *each* found that Watson's coated tablets meet the dissolution limitations of the patent claims. (*See, e.g.*, A018424-A018425; A018426-A018437; A018438-A018445; A018285-A018291; A1000-A1007; A1264-A1266; A2015-A2016.) In fact, Watson's own expert witness, Dr. Maurin, conceded that the test results Watson itself generated show that Watson's coated tablets "met the [dissolution] requirements of the patents-in-suit." (A017611-A017615 at 248-256, 320.)

Watson did not dispute that these samples meet the dissolution limitations. Rather, in an attempt to downplay this evidence, Watson contended at trial that these infringing test results related to "outliers" and that this somehow negated the fact that tablets produced according to its ANDA specifications infringe the asserted patent claims. (*See, e.g.*, Watson's Br. at 46-51.) Even if there were any merit to such an argument, however, these infringing test results are not "outliers." In one commercial lot alone, at least 28% of the tablets tested were found to meet

the dissolution limitations of the claims.[4] (*See, e.g.*, A2212-A2214; A1001-A1002, A1005-1007; A018438-A018445; A018897; A018424-A018425; A018898-A018899.) Watson offers unsupported criticism of Ferring's dissolution test methods, notwithstanding Dr. Williams unrefuted testimony supporting this testing. (*See, e.g.*, A1000-A1007; A1264-A1266; A2015-A2016.) Nevertheless, even if one only looks at the testing done by Watson and its outside laboratory, 16% of the tablets in commercial lots 3 and 4 meet the claim limitations. (A2212-A2214; A1000-A1002; A018424-A018425; A018426-A018437; A018896, A018898-A018899.) Such a large percentage of infringing tablets can hardly be called "outliers," and thus the district court properly rejected this argument.

Watson also tried to downplay these dissolution results by arguing that the USP test method recited in the patent claims requires the testing of six samples. (Watson's Br. at 48-51.) This was a new argument Watson attempted to raise at trial, and it conflicted with Watson's position earlier in the litigation that the USP

[4] The district court excluded evidence from one laboratory for reasons different than Watson's unfounded criticisms on appeal. Ferring disagrees that this exclusion was proper as the testing was performed in accordance with the method recited in the patent claims. Ferring notes that, with that evidence, the total percentage of coated tablets that meet the claim limitation is as much as 35% in this single commercial lot. (A2212-A2215; A1001-A1007; A018438-A018445; A018424-A018425; A018285-A018291.)

test method is properly conducted on individual tablets.[5] (*See, e.g.*, A924-A925; A018541-A018542 at ¶¶ 1, 2, A018545 at ¶¶ 15, 17; *see also, e.g.*, A920-A924, A1264-A1265.) In addition, this argument relies on the "Acceptance Table" in the USP, which evaluates "Q" values, specific dissolution parameters set forth in product monographs, and thus has no bearing on the test method recited in the claims. The claims do not specify any "Q" value or reference any monograph and therefore the district court properly excluded any expert testimony based on the acceptance table. (*See, e.g.*, A921-A924.) Moreover, as Ferring also demonstrated at trial, Watson's own Dr. Maurin did not apply the acceptance table in his expert report and thus had no basis to offer any such opinions at trial. (A1508-A1511.) Accordingly, the district court refused to accept this argument, and Watson does not demonstrate any error in that determination.

Watson is also wrong in raising the related argument that the district court "tentatively" found that the acceptance table applied to assessing infringement under 35 U.S.C. § 271(e) and thus required the testing of 6 samples. (Watson Br. at 50-51.) As the district court explained:

> On 271(e) I think all that you have to show, you don't have to meet the acceptance table. All you have to show

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[5] In fact, Watson itself has conducted dissolution testing according to this USP method using fewer than six samples. (*See, e.g.*, A1702-A1704; A014545-A014551 at col. 7 lines 48-53; A018383.)

> is that there is a good probability of the permitted ANDA to violate the terms of the patent.

(A2311.) The district court agreed that Ferring had made such a showing.

Finally, Watson contends that Ferring failed to prove its alternative theory that Watson's generic tablets meet the claimed dissolution profiles under the doctrine of equivalents. (Watson's Br. at 51-52.) Watson acknowledges Dr. Williams' testimony on how the dissolution results from Watson's generic tablets in simulated gastric fluid ("SGF") and pH 6.8 show that its tablets perform substantially the same release modifying function in SGF and pH 6.8 as in water in substantially the same way by slowing the dissolution of tranexamic acid from the formulation to release the same result of the desired dissolution profile and associated benefits. (*See, e.g.*, A1030-A1038; A018735-A018736; A019012; A019097.) Watson contends, however, that Ferring did not offer any opinion on the insubstantiality of the differences. (Watson's Br. at 51.) This argument overlooks Dr. Williams subsequent testimony that the use of SGF and pH 6.8 is insubstantially different from the use of water for assessing the tablet's dissolution profile. (*See, e.g.*, A1034:8-A1035:3; A1037:19-A1038:1; A018736-A018737.) As Dr. Williams explained, because the purpose of the dissolution limitation in the patent claims is to specify a formulation that will give a specific delayed release in the gastrointestinal tract, the use of SGF, which mimics the stomach environment,

and pH 6.8, which mimics the lower intestine environment, is insubstantially different from using water in this testing. (*See, e.g.*, *id.*)

For at least the reasons above, Watson's coated tablets meet all the claim limitations and therefore infringe the assert claims.

B. The Court Properly Found That the Claims of the Patents-in-Suit are Valid

Watson argues that the district court erred by finding the asserted claims non-obvious. The trial record demonstrates, however, that Watson failed to carry its burden of proving that the patent claims are obvious by clear and convincing evidence. *See Abbott Laboratories, Inc. v. Sandoz, Inc.*, 544 F.3d 1341, 1346 (Fed. Cir. 2008) (citing 35 U.S.C. § 282 and noting that a defendant raising an invalidity defense bears a "heavy burden of persuasion" requiring proof of the defense by clear and convincing evidence).

In asserting obviousness, Watson relied on references that fall into two categories. The first group of references concerns immediate release 500 mg tranexamic acid tablets. (*See, e.g.*, A2026-A2038; A018828-A018841.) These references do not teach or suggest the claimed 650 mg formulations containing modified release materials with certain dissolution limitations. (*See, e.g.*, *id.*) In addition, these references teach away from using the higher dose of 650 mg. (*See, e.g.*, *id.*) The second group concerns modified or extended release formulations. (*See, e.g.*, *id.*) These references do not teach the specific formulations or

dissolution limitations of the patent claims and further teach away from the claimed formulations that delay the release of the active ingredient in the stomach while delivering the active ingredient to the bloodstream in a manner comparable to an immediate release formulation. (*See, e.g., id.*)

Ferring's experts in fact presented unrebutted testimony that this aspect of the claimed formulations is unique and unknown in the prior art. (*See, e.g.*, A2025-A2026; A2168.) Indeed, Ferring's pharmaceutical formulation expert, Dr. Williams, and Ferring's pharmacokinetics expert, Dr. Sawchuk, each testified that they had never previously seen such a formulation, and Watson declined to offer any testimony to the contrary. (*See, e.g., id*.) Accordingly, the district court properly concluded that Watson had not shown the asserted claimed to be obvious. (*See, e.g.*, A926-A932; A928-A932; A1280-A1286; A2024-A2038; A2040-A2069; A2161-A2168; A018671; A018828-A018880.)

a. Watson's Conclusory Arguments Are Unsupported By the Trial Record

Ignoring the unique and unprecedented nature of the claimed formulations, Watson wrongly contends that "each element of the claims is disclosed in the prior art." (Watson's Br. at 62.) Watson's argument is directly refuted by the fact that it cannot identify these claim limitations in the prior art. In particular, while 500 mg immediate release tranexamic acid formulations were previously known, Watson cannot identify any prior teaching or suggestion of the unique formulations

disclosed and claimed in the patents-in-suit. Watson also cannot identify any prior art teaching of a 650 mg tranexamic acid formulation, any tranexamic acid formulation containing the type and amount of modified release material specified by the patent claims, or any tranexamic acid formulation having the claimed dissolution profile. Nor does the prior art suggest any such formulation.

b. The Prior Art Taught Away from 650 mg Dosages

Watson argues a 650 mg tablet formulation would have been "an obvious and pragmatic choice" to reduce frequency of administration to three times daily. (Watson's Br. at 64.) This argument directly conflicts with Watson's other assertion that 500 mg prior art dosage forms were already administered three times daily. (*Id*. at 63-64.) This argument is also belied by the fact that the references Watson cites disclose numerous different 500 mg formulations, but not a single higher tablet strength, much less a 650 mg formulation. (*See, e.g.*, A2026-A2031; A2033-A2038; A2041-A2044; A018828-A018832; A018835-A018836; A018838-A018841.)

Watson offers similar unsupported and contradictory reasoning in contending that "a [650 mg] dose would…address any concerns about adverse side effects." (Watson's Br. at 64.) The documents Watson cites in its obviousness analysis indicate exactly to the contrary. For example, the Cameron article cited by Watson's expert Dr. Kibbe teaches that the incidence of adverse side effects is

dose related, suggesting, if anything, a dosage strength lower than the 500 mg formulation discussed. (*See, e.g.*, A018942-A018946; A2037-A2038; A018841.) Likewise, the "CPMP" document cited by Watson and Dr. Kibbe also teaches that gastrointestinal side effects are dose-dependent. (*See, e.g.*, A13635; A018831.) Watson attempts to obfuscate this issue in its brief by citing a document relating to sustained release granular preparations. That reference says nothing, however, about whether an increased dose of any amount for any drug would address side effects, let alone whether a 650 mg dose of tranexamic acid would address such issues. (*See, e.g.*, A14480 at col. 1 lines 15-25; A2031-A2033; A018833-A018834.)

As the district court correctly noted, "[n]one of the prior art discusses [a dosage of 650 mg tranexamic acid], nor does any of the prior art motivate to a higher dosage. In fact, it motivates just the opposite direction." (A2308.) Watson's brief fails to identify any error in this finding.

c. The Claimed Dissolution Limitations are Nonobvious

Watson also does not identify any prior art reference disclosing the dissolution limitations of the patent claims. Rather, Watson again contends in conclusory fashion that these limitations were obvious. (Watson's Br. at 65-66.) For example, Watson relied at trial on its expert Dr. Kibbe, who provided the circular analysis that: "[t]he dissolution rate is a target based on other

considerations you've decided that you want to have a dissolution rate at a given amount, then what you do is you do routine testing . . ." (A1795:16-24.) In other words, if you know your target dissolution rate, you can achieve it through experimentation. But Dr. Kibbe failed to provide any explanation as to why one would have chosen the specific dissolution limitations of the patent claims. (*See, e.g., id*.) Dr. Kibbe's vague comment that this rate must have been based on other unidentified "considerations" falls woefully short of Watson's burden of clear and convincing evidence.

Watson repeats this same circular and conclusory analysis in its brief, contending that "[t]he release profile is simply a collection of observed laboratory values" that allegedly may be predicted from the "addition of a release-modifying polymer." (Watson's Br. at 65-66.) This again completely fails to address why one of ordinary skill in the art would choose the specific release profile of the patent claims. Watson further cites to a pamphlet from Dow Chemical, arguing that one "could predict the dissolution rate and time of a tablet using the percentages by weight of hydroxypropylcellulose." (*Id*. at 66.) But again Watson does not explain how one could make such a prediction and, even if one could, how one would choose the claimed dissolution profile. Nor does Watson attempt to show how the Dow pamphlet allegedly renders the specific dissolution profiles of the patent claims obvious. (*See, e.g.*, A2035:3-19; A018837.)

Watson concludes its discussion by alleging that it is "clinically meaningless . . . how a tablet releases an active ingredient in water, outside the body . . ." (Watson's Br. at 66.) This directly conflicts, however, with Watson's argument that this dissolution profile allegedly would have been an obvious choice. Watson's unsupported attempt to disparage this aspect of the invention also conflicts with the trial record, which establishes that such water based testing is routinely used to evaluate drug products. (*See, e.g*, A2168.) Moreover, as noted above, Ferring's experts offered unrebutted testimony that the claimed formulations, with the specified dissolution limitations, are unique and unprecedented in that they yield a delayed release in the stomach, minimizing side effects, while exhibiting pharmacokinetics equivalent to an immediate release formulation of the same dose. (*See, e.g.*, A2168; A2025-A2026.)

d. The Type and Amount of Modified Release Materials is Nonobvious

Watson again cannot identify any support for its multiple conclusory statements that the prior art allegedly taught the claimed formulations containing modified release materials. For example, Watson contends that the '411 patent "provides the motivation for using modified release materials with tranexamic acid because use of modified release materials was thought to decrease adverse side effects due to high blood levels, as well as to decrease dosage strength and frequency." (Watson's Br. at 65.) But the '411 patent does not teach a single

example of a tranexamic acid formulation. (*See, e.g.*, A2031-A2033; A018833-A018834.) Moreover, the '411 patent's teaching of avoiding high blood levels and decreasing dosage strength points directly away from the formulations of the patent claims, which provide an *increased* dose as compared to the prior art and also yield *higher blood levels* than those exhibited by immediate release formulations. (*See, e.g.*, *id*.)

Further, Watson cannot identify a single reference teaching the specific type and amount of modified release materials recited in the patent claims. Watson relies on references relating to immediate release tranexamic acid formulations that do not disclose the amounts of modified release polymers or any other inactive ingredients used in these formulations. (*See, e.g.*, A2026-A2031; A2033-A2038; A018828-A018832; A018835-A018836; A018838-A018841.) These references also do not teach how one can modify the release of tranexamic acid using any modified release polymers or other materials. (*See, e.g.*, *id*.) Watson additionally relies on the Handbook of Pharmaceutical Excipients reference for an alleged teaching of the use of 15-35% by weight hydroxypropylmethylcellulose. (Watson's Br. at 65.) This reference does not, however, teach using this polymer in tranexamic acid formulations nor does it teach achieving the claimed dissolution profiles. Watson further fails to inform this Court that the district court declined to consider this reference in connection with Watson's obviousness arguments,

because Watson had not identified the Handbook of Pharmaceutical Excipients in its Local Rule Patent Contentions or in its statement pursuant to 35 U.S.C. § 283. (A1788-A1789; A1790:8-14.) Therefore the district court correctly found that Watson could not rely on this reference in support of its obviousness allegations.

e. The Dependent Claims, Like the Independent Claims, Would Not Have Been Obvious

Watson again relies on conclusory arguments in contending that the dependent claims would have been obvious. For example, Watson argues that claims 5, 8 and 9 of the '795 patent are invalid "based on the disclosure of tranexamic acid formulations rendering the independent claims invalid." (Watson's Br. at 68.) This vague statement does not explain how these references teach the additional limitations in the claims and thus cannot possibly satisfy Watson's burden of proof. That is especially true given that the prior art was silent as to the amounts of inactive ingredients employed in those formulations.

Watson similarly contends, without support, that the pharmacokinetic parameter limitations in the dependent claims are "just characteristics" of the formulations and were "disclosed and expected from the prior art." (Watson's Br. at 68.) But the prior art did not disclose any 650 mg formulations and, for at least this reason, the pharmacokinetic parameters of the prior art were not the same as or predictive of the formulations of the patent claims. Watson further fails to point out that the district court rejected any opinion by Dr. Kibbe attempting to

interpolate the claimed pharmacokinetic parameters, including C_{max} values, from the distinct C_{max} values associated with 500 mg immediate release formulations. (*See, e.g.*, A1807-A1808.) Watson does not identify any error in the district court's exclusion of this evidence, and the trial record in fact supports this exclusion. (*See, e.g.*, A2162-A2167.)

As Ferring's expert, Dr. Sawchuk, explained, one would not be able to predict the pharmacokinetic parameters associated with 650 mg formulations of the patent claims, which also contain modified release materials, in light of pharmacokinetic parameters associated with 500 mg immediate release formulations. (*See, e.g.*, A2162-A2167.) Dr. Sawchuk further refuted Watson's argument that these parameters were allegedly obvious because the *inventors* were able to predict them using a "well-known computer program." (Watson's Br. at 71.) While predictions by the patent inventors are not probative of what would be obvious to one of ordinary skill in the art, Dr. Sawchuk explained one could not use this program to predict anything without making various assumptions. (*See, e.g.*, A2175:10-A2178:2.)

f. Secondary Considerations Support the Non-Obviousness of the Claimed Inventions

Watson argues that Ferring provided no evidence to support various secondary considerations. (Watson's Br. at 72.) Again, Watson ignores the extensive evidence of record. For example, Dr. Heasley offered testimony and

documentary evidence establishing there was a long-felt and unmet need for a treatment for menorrhagia that avoided adverse events. (*See, e.g.*, A765-767; A778-A783; A796-A802; A018468-A018496; A018666-A018669.) Indeed, as discussed above, the FDA recognized this long-felt need and Lysteda®'s ability to meet this need in granting the Lysteda® NDA fast-track status. (*See, e.g.*, A804-A807; A018451-A018467; A018448-A018449.)

Further, contrary to Watson's assertions (Watson's Br. at 9), the approved Lysteda® package insert indicates that Lysteda® surprisingly does *not* exhibit the gastrointestinal side effects associated with prior immediate release formulations. (*See, e.g.*, A012955 at Table 2 (reporting adverse events, which does not include nausea, vomiting and diarrhea); *see also, e.g.*, A941; A016831-A016840.) Watson's misleading arguments to the contrary are based on draft labeling documents that were not approved by the FDA and also portions of the approved labeling that detail "worldwide" post-marketing experiences more broadly directed to experiences with "tranexamic acid" that include the well-known side effects associated with immediate release tranexamic acid formulations sold in other countries.[6] The superior side effect profile of Lysteda® is amply documented in

[6] That this section of the labeling is directed to experiences with immediate release tranexamic acid sold abroad is demonstrated by the fact that this section of the labeling was first introduced in the draft labeling that Watson cites. (A011541) (continued…)

the FDA approved labeling, the scientific literature, and Watson made admissions in this regard in its own ANDA submissions. (*See, e.g., id.*; A012859-A012866; A013879.)

In addition, Watson ignores the *unrebutted* testimony of Dr. Williams and Dr. Sawchuk that highlights the unexpected results of the claimed formulations. For example, both Dr. Williams and Dr. Sawchuk testified that it was a surprising result that the claimed formulations, which exhibit modified release dissolution profiles *in vitro*, are bioequivalent to an immediate release formulation. Indeed, Dr. Williams testified that he was "not aware of any other pharmaceutical formulation that exhibits modified release dissolution properties in vitro but is bioequivalent to an immediate release formulation in vivo." (A2025-A2026.) Dr. Sawchuk similarly stated, "I don't know of any other example of bioequivalence between two products, immediate release and a more slowly dissolving modified release product." (A2168.)

(…continued)
This draft labeling was generated *before* Lysteda®'s launch and thus before there were any post-marketing reports concerning Lysteda®.

C. The District Court Properly Entered an Injunction and Order Resetting Watson's ANDA Approval Date

1. The District Court Correctly Awarded the Relief under 35 U.S.C. § 271(e)(4)

Based on its findings of infringement, the district court correctly ordered the mandatory relief and permanent injunctive relief under 35 U.S.C. §§ 271(e)(4)(A) and 271(e)(4)(B), respectively. Watson offers no valid authority to contest this relief.

a. Section 271(e)(4)(A) Mandates Resetting Watson's ANDA Approval Date

Watson argues that § 271(e)(4)(A) is "a de facto injunction" (Watson's Brief at 57), suggesting that this characterization should somehow strip the statute of its plain and unambiguous meaning. Watson is wrong. The relief in § 271(e)(4)(A) is *mandatory* upon a finding of infringement:

> "For an act of infringement described in paragraph (2)—
>
> (A) the court ***shall order*** the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed."

35 U.S.C. § 271(e)(4)(A) (emphasis added). This language is plain and unambiguous. Absent "extraordinary showing of contrary intentions," the plain language of the statute controls. *LSI Computer Sys., Inc. v. United States Int'l Trade Comm'n*, 832 F.2d 588, 590 (Fed. Cir. 1987) (quoting *Garcia v. United States*, 469 U.S. 70, 75 (1984)).

This is particularly true where, as here, the plain language is the result of a legislative compromise struck between competing interest groups. *See Barnhart v. Sigmon Coal Co., Inc.*, 534 U.S. 438, 460-62 (2002). The Hatch-Waxman Act represents a compromise between groups aligned with generic manufacturers and innovative pharmaceutical companies. The Act thus provides significant advantages to generic applicants, including allowing them to rely on the innovator's safety and efficacy data, while also providing advantages to innovators, including mechanisms to enforce their patent rights. The Act thus provides that, upon a finding of infringement, the court "shall" reset the ANDA approval date, barring any sales.

Moreover, the term "shall…normally creates an obligation impervious to judicial discretion." *Lexecon Inc. v. Milberg*, 523 U.S. 26, 35 (1998); *see also Merck & Co., Inc. v. Hi-Tech Pharmacal Co., Inc.*, 482 F.3d 1317, 1322 (Fed. Cir. 2007) ("[u]se of the word 'shall' in a statute generally denotes the imperative."). Accordingly, Watson's frivolous contention that this remedy is "discretionary" conflicts with the statute's plain language.

Watson's argument also belies this Court's precedents, which confirm that the remedy under section 271(e)(4)(A) is mandatory. For example, in *In re Omeprazole*, this Court explained that section 271(e)(4)(A):

> provides an additional type of relief after a finding of infringement under section 271(e)(2) by ***requiring*** the district court to "order the

> effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed."

536 F.3d 1361, 1367 (Fed. Cir. 2008) (citing 35 U.S.C. § 271(e)(4)(A)). *See also Bristol-Myers Squibb Co. v. Royce Laboratories Inc*., 69 F.3d 1130, 1135 (Fed. Cir. 1995) ("If the court determines that the patent is not invalid and that infringement would occur… the patent owner is *entitled* to an order that FDA approval of the ANDA … not be effective until the patent expires." (emphasis added)).

Watson ignores these precedents and instead relies on a district court case—an opinion by Judge Posner, sitting by designation in the Northern District of Illinois. (Watson's Brief at 59.) That decision was ***vacated*** by the full Federal Circuit sitting en banc and later ***superseded*** by another three-judge Federal Circuit panel. *SmithKline Beecham Corp. v. Apotex Corp*., 403 F.3d 1328 (Fed. Cir. 2005) (*en banc*) (vacating affirmance of trial decision); 403 F.3d 1331 (Fed. Cir. 2005) (superseding opinion). Watson fails to identify any valid authority for its position that the remedy under § 271(e)(4)(A) is discretionary.

Relying on another district court case, Watson wrongly contends that when infringement is based on a commercial product, a resetting order is inappropriate. (Watson's Brief at 59 (citing *Sanofi-Aventis Deutschland GmbH v. Glenmark Pharm. Inc., USA*, 821 F. Supp. 2d 681, 697 (D.N.J. 2011)).) The *Sanofi-Aventis*

decision has no authority over this Court, however, and certainly cannot trump this Court's decisions to the contrary. The *Sanofi-Aventis* decision is also directly contrary to the plain language of the Hatch-Waxman Act as well as the associated legislative history, which explains:

> If the infringing party has begun commercial marketing of the drug, damages and other monetary relief and injunctive relief may be awarded for the infringement and to prevent further infringement. ***In addition, the FDA would be mandated to change the effective date of the approved ANDA to the expiration date of the infringed patent***.

H.R. Rep. No. 98-857, at 46 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2679 (emphasis added). This Court should therefore reject Watson's unsupported arguments.

b. *eBay* Does Not Apply to Section 271(e), But Even if It Did, the District Court Considered the *eBay* Factors

Watson further argues that the district court erred because it allegedly failed to consider the *eBay* factors before ordering relief under §§ 271(e)(4)(A) and 271(e)(4)(B). (Watson's Brief at 55, 57.) Watson is again wrong. *eBay* is not applicable to the remedies set forth in § 271(e). In *eBay Inc. v. MercExchange, LLC*, 547 U.S. 388 (2006), the Supreme Court considered § 283 of the Patent Act, not § 271(e). As the Supreme Court explained, § 283 states that injunctions may issue "in accordance with the principles of equity." 547 U.S. at 392. The Supreme

Court's interpretation of this provision has no bearing on the distinct remedies in § 271(e), which do not recite or suggest that injunctions may only be issued in "accordance with the principles of equity." Indeed, Watson does not cite *any authority* for applying *eBay* to an injunction under § 271(e).

The injunction provision in 35 U.S.C. § 271(e)(4) does use the permissive term "may," but this provision is available "to prevent the commercial manufacture, use, offer for sale or sale," a prohibition that may not always be necessary given the other mandatory relief in this section of the statute, such as that prohibiting the approval of infringing ANDAs. 35 U.S.C. § 271(e)(4)(B). Significantly, all of § 271(e)(4) is written to provide mandatory relief, via whatever mechanisms are necessary and appropriate, to prevent infringement of patent rights associated with New Drug Applications and Therapeutic Biologic Applications. *See* § 271(e)(4)(A) ("the court shall order the effective date . . ."); § 271(e)(4)(D) ("the court shall order a permanent injunction prohibiting any infringement of the patent by the biological product involved in the infringement . . ."). None of these provisions indicate that this relief is available only in accordance with the principles of equity.

Nonetheless, even if the *eBay* factors were applicable to injunctions issued pursuant to § 271(e), which they are not, Watson is simply wrong that the district court "explicitly refused" to consider such factors. (Watson's Br. at 55.) As

discussed above, the district court fully considered Watson's arguments and submissions, including detailed information about Ferring's Lysteda® sales before and after Watson's generic launch. (*See, e.g.*, A286-A290; A1093.) Based on this evidence, the district court specifically rejected Watson's arguments that it had failed to consider *eBay* factors such as irreparable harm and further found that Ferring would in fact suffer irreparable harm absent entry of the judgment barring further infringing sales. (*See, e.g.*, A322-A323 ("The harm is not purely economic, but also in the loss of good faith with the consuming public that comes from being an innovator with an exclusive product").) Accordingly, even under Watson's flawed § 271(e) analysis, its criticism of the district court's Judgment is meritless.

2. The District Court Correctly Awarded a Permanent Injunction under 35 U.S.C. § 283

In attempting to challenge the permanent injunction issued under § 283, Watson, once more, contends that the district court did not "consider[] a single *eBay* factor." (Watson's Br. at 55.) Yet, as discussed above, this contention is simply false. The district court specifically rejected Watson's arguments that it had failed to consider *eBay* factors such as irreparable harm and further found that Ferring would in fact suffer irreparable harm absent entry of the judgment barring further infringing sales. (*See, e.g.*, A286-A290; A322-A323.)

Citing *Johns Hopkins Univ. v. CellPro, Inc.*, 152 F.3d 1342, 1366 (Fed. Cir. 1998), and *Joy Techs., Inc. v. Flakt, Inc.*, 6 F.3d 770, 777 (Fed. Cir. 1993), Watson

argues that injunctions "should not . . . enjoin . . . products that do not infringe." (Watson's Br. at 56.) But as discussed above, Ferring proved infringement at trial. Further, the cases cited by Watson do not stand for the proposition that an infringer is allowed to use, manufacture, or sell infringing products because of a possibility that the infringer might also use, manufacture, or sell non-infringing products. In fact, just as this Court noted in *Johns Hopkins*, Ferring has shown Watson's "propensity to infringe" such that an injunction is "necessary to prevent infringement." *Johns Hopkins*, 152 F.3d at 1366, n. 31.

D. Watson Asks This Court To Make Various Factual Findings

Watson suggests in several places that the district court's factual findings are unclear and therefore asks this court to make those findings in the first instance. For example, it asks this Court to decide whether its allegedly ANDA amendment to its hardness specification, which the district court properly excluded, proves that Watson's uncoated tablets do not infringe. (*See, e.g.*, Watson's Br. at 53-54.) These repeated requests that this Court make factual determinations in the first instance are not appropriate on appeal and suggest that the present appeal is premature in light of the fact that the district court has not yet entered its Findings of Fact and Conclusions of Law. And Watson's request that this Court decide factual issues based on alleged evidence introduced post-trial is particularly inappropriate because Ferring has had no opportunity to litigate these issues.

V. CONCLUSION

For the foregoing reasons, Ferring respectfully requests that the Court affirm the district court judgment finding that Watson's uncoated and coated tablets infringe the assert claims of the patents-in-suit and that the assert claims are valid.

Respectfully submitted,

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May 14, 2014

CERTIFICATE OF SERVICE

I certify that I electronically filed the foregoing **CORRECTED NON-CONFIDENTIAL BRIEF FOR PLAINTIFF-APPELLEE FERRING B.V.** using the Court's CM/ECF filing system. Counsel registered with the CM/ECF system have been served by operation of the Court's CM/ECF SYSTEM per Fed. R. App. P. 25 and Fed. Cir. R. 25(a) and by electronic mail on this 14th day of May 2014.

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I certify that the foregoing **CORRECTED NON-CONFIDENTIAL BRIEF FOR PLAINTIFF-APPELLEE FERRING B.V.** contains 13, 920 words as measured by the word processing software used to prepare this brief.

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